Preparing IISs for COVID-19 Response

September 21, 2020 Version 1

Contents

| Introduction | 1 |
|--|----|
| Awardee Response Activities | 2 |
| Activity Categories | 2 |
| Staff Considerations | 3 |
| Funding Considerations | 3 |
| Activity Prioritization | 4 |
| Activities Overview | |
| Update System and Improve Capacity | 5 |
| Address Defects and Enhancements | 5 |
| Adopt Vaccine Administration Tracking Method | ε |
| Target Critical Populations | 7 |
| Conduct Provider Outreach | 8 |
| Enroll and Onboard Providers | 8 |
| Align and Implement Policies for Data Sharing | g |
| Collect and Report Data | 10 |
| Improve Data Quality | 11 |
| Manage Vaccine Ordering and Inventory Tracking | 12 |
| Approach to Developing an Individual Awardee Technical Assistance Assessment | 12 |

Introduction

Awardees have begun preparing for the significant undertaking of getting immunization information systems (IISs) ready for COVID-19 vaccination tracking efforts. CDC is committed to supporting awardees in COVID-19 vaccination response efforts and sharing the latest available information. This document supplements the <u>COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (Playbook)</u>. It provides a more in-depth look at activities highlighted in Section 11, "COVID-19 Requirements for Immunization Information Systems or Other External Systems," as well as considerations and guidance for IIS activities spanning nearly all aspects of COVID-19 vaccination response efforts.

Activities included in this document reflect the most recent information to date and focus on preparing the IIS. COVID-19 vaccination response efforts are rapidly evolving, and recommendations for some

activities may change as additional guidance becomes available. This document will be updated as additional guidance related to IIS activities is released.

CDC will partner with each awardee to develop a tailored technical assistance assessment that will identify IIS activities for the awardee to include in their response plans and areas for support based on their IIS's current operational capabilities and technical environment. CDC is also creating a COVID-19 resource toolkit awardees can use in their response efforts.

Awardee Response Activities

Activity Categories

The following 10 categories of pandemic response activities relate to IIS functionality or the ability of the IIS to collect, submit, and exchange COVID-19 vaccination data. Each category includes the expected outcome of successfully completing the associated activities and lists the corresponding section(s) of the Playbook.



UPDATE SYSTEM AND IMPROVE CAPACITY

Jurisdiction's IIS infrastructure meets COVID-19 response data exchange, storage, and reporting requirements

Playbook Reference: Section 11



ENROLL AND ONBOARD PROVIDERS

Jurisdiction enrolls and onboards providers to COVID-19 vaccination program and IIS for timely data exchange

Playbook References: Section 5, Section 11



ADDRESS DEFECTS AND ENHANCEMENTS

Jurisdiction's IIS operates as expected to support COVID-19 vaccination tracking efforts

Playbook Reference: Section 11



ALIGN AND IMPLEMENT POLICIES FOR DATA **SHARING**

Jurisdiction has necessary policies in place to facilitate sharing data with CDC and other jurisdictions

Playbook Reference: Section 11



ADOPT VACCINE ADMINISTRATION TRACKING METHOD

method that meets defined standards

Playbook References: Section 9, Section 10, Section 11



COLLECT AND REPORT DATA

Jurisdiction implements a vaccine administration tracking Jurisdiction's IIS collects, reports, and submits data to satisfy CDC and jurisdictional reporting requirements

Playbook References: Section 9, Section 11, Section 15



TARGET CRITICAL POPULATIONS

Jurisdiction identifies mechanisms to reach critical populations during early targeted vaccination efforts

Playbook References: Section 4, Section 11, Section 12



IMPROVE DATA QUALITY

Jurisdiction's IIS data quality meets defined standards for the COVID-19 response

Playbook Reference: Section 11



CONDUCT PROVIDER OUTREACH

Jurisdiction has optimal provider participation in IIS for early critical and general population vaccination efforts

Playbook References: Section 5, Section 11, Section 12



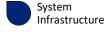
MANAGE VACCINE ORDERING AND INVENTORY **TRACKING**

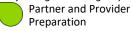
Jurisdiction has processes for allocating vaccine to provider sites and tracking inventory

Playbook References: Section 7, Section 11

Legend

The 10 activity categories are grouped together based on common themes:









Staff Considerations

When selecting activities, awardees need to assess current staff capacity and resources required to complete and sustain the activities. Each jurisdiction will approach staffing differently, taking into consideration its own circumstances.



Staffing Assessment

To determine staffing and resource needs and develop a plan to address capacity gaps, awardees are encouraged to consider the following questions at the outset of their response efforts and revisit these questions as plans develop:

- What level of staff support will be needed to complete the activities?
- Does the jurisdiction currently have the required level of staffing?
- If so, does current staff have the right skills and expertise to complete the activities?
- What options does the jurisdiction have to increase staffing?
 - Can staff from activities not critical to the response be reassigned to support critical activities?
 - Can staff from other areas of the health department (e.g., emergency response) assist?

Funding Considerations

CDC acknowledges that achieving certain activities depends on available funding. Awardees are encouraged to examine their 317/VFC cooperative agreement (CoAg) workplan to identify potential opportunities to use CoAg funding to support COVID-19 response activities. The following table provides examples of how required CoAg activities align with COVID-19 response activities.

| COVID-19 Response Activities | Applicable CoAg Required Activities ¹ |
|--|--|
| Update system and improve capacity | D2a, D2b, D2d |
| Address defects and enhancements | D2a, D2d |
| Adopt vaccine administration tracking method | N/A |
| Onboard providers | D1c |
| Conduct provider outreach | C1a, C2d, D1a, E3a, E3b |
| Target critical populations | E1b, E3a |
| Align and implement policies for data sharing | D1d |
| Collect and report data | D1b, D1c, D1d, D1e, D2c |
| Improve data quality | B1c, D1a, D2c, D2e, D2f |
| Manage vaccine ordering and inventory tracking | C4c |

¹ The CoAg Required Activities correspond to various chapters in the 2020 Immunization Program Operations Manual (IPOM). The chapter topics are as follows:

[•] Chapter A – Program Management and Sustainability

Chapter B – Program Effectiveness

[•] Chapter C – Vaccine Access and Management

Chapter D – Immunization Information Systems and Technology

[•] Chapter E – Communication, Partnership, and Education

[•] Chapter F – Provider Quality Improvement

In addition to 317/VFC CoAg funding, awardees should explore all available resources, including:

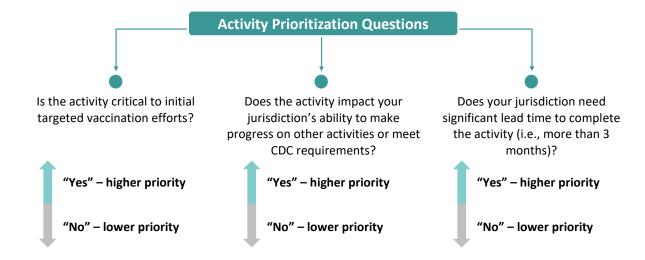
- Supplemental Funding for IP19-1901 Immunization and Vaccines for Children Cooperative Agreement Recipients
- Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious
 Diseases (ELC)
- CDC Coronavirus Preparedness and Response Supplemental Funding and Update
- Influenza Season Early Preparedness Funding

Awardees are encouraged to coordinate with their IIS consortium to identify opportunities for costsharing on system updates and enhancements. CDC can help awardees determine which funding mechanisms apply to their respective preparation efforts as part of the individual technical assistance assessment.

Activity Prioritization

The response activities encompass both critical and general population vaccination efforts. While this document is intended to be comprehensive and include all IIS activities that are important to COVID-19 vaccination response efforts, not all activities will apply to all awardees. Awardees can use this document to assess where they are in their preparation efforts and prioritize activities that need to be accomplished in both the near and long term.

CDC will collaborate with each awardee to develop individual technical assistance assessments to help focus their efforts and identify areas for support. Awardees can also use the following questions to guide prioritization of response activities. Awardees' responses to these questions will indicate whether an activity should be prioritized in the near term (i.e., "higher priority") or whether an activity should be planned for longer-term implementation, if it has not already been completed (i.e., "lower priority").



Activities Overview

This section outlines activities for each overarching category listed above. Activities are further organized in stages, including planning (Plan), implementation (Implement), and sustaining (Sustain). This scheme is intended to help awardees sequence their efforts and guide them through each stage.

Each activity category includes references to the corresponding section of the Playbook for additional guidance and alignment with broader response planning efforts. CDC also noted where an awardee's ability to pursue certain activities may depend on other factors, such as identifying additional funding.

Note that a "\" symbol indicates the associated activity impacts early targeted vaccination efforts focused on critical populations.

Update System and Improve Capacity

| Plan | Implement | Sustain |
|--|--|--|
| Develop a plan to ensure IIS capacity for data exchange and storage (e.g., upgrade hardware/software, transition data to cloud storage). Develop a plan to update to latest version of the IIS platform and the dependent software/hardware, as applicable. | Engage vendors to incorporate and implement system updates into a new or modified contract. Test and ensure timely availability of upgrades in production. Develop communication and training materials for users affected by system changes. Purchase and implement necessary hardware/software. Ensure that backup and storage capacity are adequate, operational, and tested. | Monitor system updates for defects. Assess IIS capacity for data exchange and storage on a routine basis. |

Related Section of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

Section 11: COVID-19 Requirements for IISs or Other External Systems

Awardee Dependencies:

- Awardee will determine funding available to support IIS platform updates.
- Awardee will determine resources available for system updates and capacity expansion.

Address Defects and Enhancements

| | Plan | Implement | Sustain |
|---|---|---|--|
| • | Prioritize addressing defects and enhancements needed for COVID-19 response efforts and develop a plan for addressing them. Determine costs for enhancements and identify | Direct and oversee the IIS vendor or central IT in implementing identified enhancements, including modifying contracts or service-level agreements as needed. | Monitor system performance to identify and document defects and possible enhancements. Review the defect and enhancement log and the assigned priorities routinely. |
| | funding mechanisms. | Test and ensure timely availability of enhancements | |

| Identify opportunities to coordinate with IIS consortia on priorities, cost sharing, and vendor engagement. Identify opportunities to coordinate with IIS production. Update training materials and reference guides. Communicate defect fixes and implementation. | Plan | Implement | Sustain |
|---|--|--|---|
| users. | coordinate with IIS consortia on priorities, cost sharing, and | production. Update training materials and reference guides. Communicate defect fixes and enhancements with end | vendor and consortium to share costs of enhancement development and |

Related Sections of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

• Section 11: COVID-19 Requirements for IISs or Other External Systems

Awardee Dependencies:

• Awardee will determine funding available to support IIS enhancements.

Adopt Vaccine Administration Tracking Method

| Į | IVICUIOU | | |
|---|--|---|--|
| | Plan | Implement | Sustain |
| | Select a vaccine administration tracking method that meets defined standards (e.g., VAMS,² IIS, or alternative solution). | Test the vaccine administration tracking method (e.g., as part of a seasonal flu clinic or tabletop exercise), including user | Monitor implementation of the vaccine administration tracking method for issues, including data collection/reporting and |
| | Develop a plan to procure/develop, test, and implement the selected | acceptance testing, load and volume testing, and security testing. | provider use. |
| | method, if not using VAMS. Develop business processes for offline use if using an internet-based tool (e.g., | Develop training and communication materials for all end users, if not using VAMS. | |
| | develop hard copies of forms, establish procedures for manual data entry). | Test and implement the backup plan to capture data in the event of limited connectivity. | |
| | Explore methods and systems (including VAMS and the IIS) to send second-dose reminders to vaccine recipients as needed. | Test and implement the selected methods and systems for sending second- dose reminders to vaccine recipients. | |

Related Sections of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

- Section 9: COVID-19 Vaccine Administration Documentation and Reporting
- Section 10: COVID-19 Vaccination Second-Dose Reminders
- Section 11: COVID-19 Requirements for IISs or Other External Systems

² Vaccine Administration Management System (VAMS) is CDC's web-based tool for supporting vaccine administration operations, and data collection and tracking

| Plan | Implement | Sustain |
|---------------------------|-----------|---------|
| Awardee Dependencies: N/A | | |
| | | |
| | | |

To be determined:

 Guidance on data and technology standards that a jurisdiction's selected vaccine administration tracking method should meet

| Target Critical Po | pulat | ions |
|--------------------|-------|------|
|--------------------|-------|------|

| Plan | Implement | Sustain |
|---|--|--|
| Coordinate with the jurisdiction's public health program to develop a strategy for reaching critical populations for targeted vaccination efforts in accordance with CDC guidance (e.g., engaging with employers if using VAMS). | Coordinate with the jurisdiction's public health program to conduct outreach to identified partners; provide guidance on vaccination of critical populations and use of the vaccine administration tracking system. | Provide ongoing support and communications to identified partners in implementing CDC guidelines on vaccination of critical populations. |
| Develop a plan to conduct outreach to identified partners involved in the critical population vaccination strategy to promote use of the vaccine administration tracking system. Develop a communication plan to promote use of the vaccine administration tracking system among the critical populations. | Enroll identified partners in the COVID-19 vaccination program, if applicable. Enroll vaccination provider sites. Conduct outreach to critical populations and disseminate relevant resources (e.g., training materials) to support use of the vaccine administration tracking system. | |

Related Sections of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

- Section 4: Critical Populations
- Section 11: COVID-19 Requirements for IISs or Other External Systems
- Section 12: COVID-19 Vaccination Program Communication

Awardee Dependencies:

• Jurisdiction finalizes vaccine administration tracking method (e.g., VAMS, IIS, or alternative method that meets data and technology requirements).

To be determined:

• Guidance on critical populations for early targeted vaccination efforts

Conduct Provider Outreach

| Plan | Implement | Sustain |
|---|---|---|
| Identify traditional and non-traditional provider sites to support critical population and general population vaccination efforts. Develop a plan for conducting outreach to identified provider sites to facilitate enrollment in the COVID-19 vaccination program and IIS. | Conduct outreach to provider sites for enrollment in the COVID-19 vaccination program. Conduct outreach to provider sites for enrollment in IIS for general population vaccination efforts. Distribute relevant training materials/resources to provider sites. | Continue to identify new provider sites to enroll in the COVID-19 vaccination program and/or IIS to support vaccination efforts. Maintain communication with provider sites. |

Related Sections of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

- Section 5: COVID-19 Provider Recruitment and Enrollment
- Section 11: COVID-19 Requirements for IISs or Other External Systems
- Section 12: COVID-19 Vaccination Program Communication

Awardee Dependencies: N/A

To be determined:

• Specific multijurisdictional providers to be served directly by CDC

Enroll and Onboard Providers

| Plan | Implement | Sustain |
|--|---|--|
| Establish mechanisms and processes for enrolling provider sites in the IIS and COVID-19 vaccination program. Develop a plan to report COVID-19 vaccination provider enrollment data to CDC. Assess the IIS onboarding queue and develop a plan to expedite onboarding of likely COVID-19 vaccination provider sites. | Ensure that provider sites enroll in the IIS and COVID-19 vaccination program, including signing COVID-19 vaccination provider agreements and addressing outstanding enrollment issues. Report COVID-19 vaccination provider enrollment data to CDC. Implement the plan to expedite onboarding of likely COVID-19 vaccination provider sites. Onboard provider sites and verify their ability to exchange data with the IIS. | Monitor the onboarding queue and provider data exchange; troubleshoot and address issues. Monitor the timeline and prepare for renewal of all IIS and COVID-19 vaccination provider agreements. |

| Plan | Implement | Sustain |
|--|-----------|---------|
| Assess processes and identify opportunities for improvement to meet anticipated provider site onboarding demand (including redesigning workflows, automating, adding tools). | | |

Related Sections of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

- Section 5: COVID-19 Provider Recruitment and Enrollment
- Section 11: COVID-19 Requirements for IISs or Other External Systems

Awardee Dependencies:

• Awardee will determine resources available to meet anticipated provider site onboarding demand.

Align and Implement Policies for Data Sharing

| Plan | Implement | Sustain |
|---|---|--|
| Assess the jurisdiction's laws/policies and develop a plan to address policy issues that prevent access to the Immunization Gateway (IZ | Implement the plan to address policy issues that prevent the jurisdiction from accessing response systems and sharing data. | Monitor the timeline and prepare for renewal of all signed legal agreements. |
| Gateway), VAMS, and other response systems. ◆ Understand the jurisdiction's process for completing legal agreements for data sharing (e.g., identify legal contacts, information they need, and their timelines for review/sign-off). ◆ Coordinate with the jurisdiction's IT policy stewards to plan for data sharing with CDC by onboarding to the IZ Gateway or submitting extracts directly to the data lake. | Coordinate with the jurisdiction's legal team to sign the CDC COVID-19 Response Data Use Agreement (DUA) and Association of Public Health Laboratories (APHL) DUA for IZ Gateway Connect. Coordinate with the jurisdiction's legal team to sign the Interjurisdictional Memorandum of Understanding for IZ Gateway Share. Coordinate with the jurisdiction's policy stewards to implement the plan for data sharing by connecting to the IZ Gateway or submitting extracts directly to the data lake. | |

Plan Implement Sustain

Related Section of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

• Section 11: COVID-19 Requirements for IISs or Other External Systems

Awardee Dependencies:

Awardee will engage jurisdiction leadership to address legal barriers to data sharing.

To be determined:

- Finalized CDC COVID-19 Response DUA
- Alternative mechanism for submitting data to CDC for jurisdictions that are unable to participate in IZ Gateway

| 0-1 | lect and | Daniel Land | D-4- |
|-----|-----------|-------------|------------------------|
| ്വ | iect and | REDOLL | пата |
| CUI | icci aiia | INCOUL | $\boldsymbol{\nu}$ uuu |

COVID-19 vaccination

reporting requirements.

| Plan | Implement | Sustain |
|---|---|--|
| Data Collection and Reporting for CDC | | |
| Develop a plan to participate in IZ Gateway Connect. Develop a plan to participate in IZ Gateway Share. Assess the ability of the IIS to receive data from VAMS. Assess the ability of the IIS to collect and send required data elements to CDC, if not using VAMS. | Participate in testing and production readiness activities for IZ Gateway Connect. Participate in testing and production readiness activities for IZ Gateway Share. Address gaps in the ability to receive data from VAMS and other national provider organizations connected to the IZ Gateway. Test and implement the process for sending required data to CDC, if not using VAMS. | Monitor data receipt and collection. Monitor the expiration dates for system certificates needed by the IZ Gateway and renew to ensure continuity of service. |
| Data Collection and Reporting for Jurisdiction | | |
| Assess existing capacity (i.e., canned reports) for responding to COVID-19 vaccination reporting requirements. Assess existing query and data analysis capacity for responding to jurisdiction's | Address gaps in the ability to collect and send required data elements to CDC. Identify and promote the use of canned reports that support COVID-19 vaccination reporting; update reports as needed. | Continue to generate coverage reports to inform and track the jurisdiction's vaccination efforts. |

Identify and modify existing

queries to support COVID-19

queries or develop new

vaccination reporting.

| Plan | Implement | Sustain |
|--|---|---------|
| Establish a plan for sharing coverage assessments with internal and external partners to promote awareness of progress in vaccination efforts. | Generate coverage assessments to inform and track the jurisdiction's vaccination efforts. | |

Related Sections of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

- Section 9: COVID-19 Vaccine Administration Documentation and Reporting
- Section 11: COVID-19 Requirements for IISs or Other External Systems
- Section 15: COVID-19 Vaccination Program Monitoring

Awardee Dependencies:

 Awardee will determine funding available to support IIS enhancements necessary to meet CDC reporting requirements.

To be determined:

 Alternative mechanism for submitting data to CDC for jurisdictions that are unable to participate in IZ Gateway

| Improve Data Quality | | |
|---|---|---|
| Plan | Implement | Sustain |
| Assess the IIS's data quality and identify issues, including jurisdiction policies, that affect COVID-19 vaccination response monitoring and reporting. Develop a plan to address identified issues and monitor data quality, particularly for CDC required data elements. Prepare to update clinical decision support (CDS) in coordination with the IIS vendor or central IT. | Implement processes to address data quality, including review and reconciliation of data collected through VAMS or alternative vaccine administration tracking system and automated matching/routine manual resolution of duplicate vaccination and patient demographic records. Implement process for tracking and addressing errors in incoming data. Update CDS when Clinical Decision Support for Immunization (CDSi) | Monitor data quality on an ongoing basis. Maintain processes that support high-quality data (e.g., through data review and reconciliation, automated matching, and routine manual resolution processes). |
| | resources for COVID-19 are updated. | |

Related Section of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

• Section 11: COVID-19 Requirements for IISs or Other External Systems

Awardee Dependencies: N/A

Manage Vaccine Ordering and Inventory Tracking

| Plan | Implement | Sustain |
|---|--|---|
| Review business processes and IIS functionality used for vaccine ordering and inventory management and identify areas for improvement. Review CDC specifications for available vaccines and develop a plan to use the IIS to order vaccine and supplies and track inventory. Assess the IIS capacity for ordering, monitoring, and managing inventory (orders, doses administered, wasted, spoiled, expired, or transferred) of vaccines and associated kits and identify gaps with CDC specifications. Assess the ability of the IIS to report vaccine inventory. Identify opportunities to adopt 2D barcode scanning technology during vaccine inventory management and administration to improve data quality and minimize transcription errors during vaccine administration. | Implement the plan to address gaps in ordering and inventory business processes. Establish processes for monitoring and replenishing provider sites' vaccine inventory and supplies. Implement the plan to address gaps in ability to report vaccine inventory in accordance with CDC requirements. Support implementation of 2D barcode scanning technology, including providing training, procuring scanners, and assessing data to identify sites in need of additional support. | Monitor ordering and inventory business processes and address emergent issues. Report vaccine inventory as required. Monitor for consistent use of 2D barcode scanning practices. |

Related Sections of COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

- Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management
- Section 11: COVID-19 Requirements for IISs or Other External Systems

Awardee Dependencies: N/A

To be determined:

• Requirements for provider-level COVID-19 vaccine inventory reporting

Approach to Developing an Individual Awardee Technical Assistance Assessment

Awardees' IISs reflect a range of maturity levels, have varying capabilities, and operate in unique environments. A single COVID-19 vaccination tracking and monitoring preparation guide will not meet all awardees' needs. Thus, CDC will collaborate with each awardee to develop individual technical

assistance assessments that will help awardees identify where to focus their response efforts based on their current progress. CDC will also use the individual assessments to identify areas of need and guide the technical assistance that CDC staff and/or partners will provide.

To develop individual awardee technical assistance assessments, CDC will consider the IIS's operational and technical environment in relation to national pandemic response needs, including:

- IIS platform and platform version
- IIS platform transition plan
- Health Information Exchange (HIE) policies and status
- IZ Gateway connection status
 - Components the awardee is planning to participate in or is currently participating in (i.e., Connect, Share, Access)
 - AIRA Measurement and Improvement (M&I) status
 - Legal agreements status
- Policies affecting IIS's ability to share data (e.g., consent laws, security policies)
- IIS data quality and reporting capabilities
- Other information provided by the awardee about its response efforts

To guide development of individual awardee technical assistance assessments, CDC will partner with awardees to leverage existing information sources, such as IIS Capability Assessments, Data Quality Reports, CDC situational awareness surveys, and CoAg applications. While collaborating with awardees on the individual assessments, CDC will validate the understanding of the IIS's current capabilities to ensure the plans accurately align with the awardee's needs.